

REMARKS

Upon entry of this response, claims 1-22 will be pending. The claims of group II (claims 14, 15 and 16) are elected in response to the restriction requirement of August 11, 2011. Claims 20 and 22 are amended herein to clarify the scope of the claims. No new matter is added.

Restriction of claims:

The Office alleges that the pending claims do not relate to a single general inventive concept under PCT Rule 13.1 because the claims are said to lack the same or a corresponding special technical feature. Thus, the Office requires Applicants to elect one of the following three groups of claims for prosecution:

Group I – Claims 1-13 are allegedly directed to isolated polynucleotides encoding mammalian pro-TGF β polypeptide wherein the polynucleotide does not encode a cysteine residue within the first ten amino acid residues of the pro-TGF β polypeptide.

Group II – Claims 14-16 are allegedly drawn to isolated polypeptides encoded by polynucleotides encoding mammalian pro-TGF β polypeptides wherein the polynucleotides do not encode a cysteine residue within the first ten amino acid residues of the pro-TGF β polypeptides.

Group III – Claims 17-22 are allegedly drawn to a method of producing mature TGF β polypeptide in a eukaryotic cell comprising culturing a cell comprising an isolated polynucleotide encoding a mammalian pro-TGF β polypeptide wherein the polynucleotide does not encode a cysteine residue within the first ten amino acid residues of the pro-TGF β polypeptide.

Traversal:

The Office characterizes the common special technical feature of the claims as “the isolated polynucleotide with any structure encoding mammalian pro-TGF β polypeptide with the exception that polynucleotide does not encode a cysteine residue within the first ten amino acid

residues of the pro-TGF β polypeptide . . ." based on the elements recited in claim 1. In view of this characterization and certain cited art, the Office asserts that the pending claims lack a special technical feature under PCT Rule 13.2, and thus, fail to satisfy PCT Rule 13.1. Applicants traverse the restriction requirement as being improper.

The Office's characterization of the claims is incorrect. Claim 1 is directed to an isolated polynucleotide encoding a mammalian pro-TGF β polypeptide, wherein the polynucleotide does not encode a cysteine residue within the first ten amino acid residues of the pro-TGF β polypeptide *and also* encodes a heterologous signal polypeptide that is in frame with the pro-TGF β polynucleotide. Therefore, the polynucleotide of claim 1 has three elements:

1. it encodes a pro-TGF β polypeptide,
2. it does not encode a cysteine residue within the first ten amino acid residues of the pro-TGF β polypeptide, and
3. it encodes a heterologous signal polypeptide that is in frame with the pro-TGF β polynucleotide.

The Office concludes that EP0373994 discloses "a recombinant method of producing a TGF β variant where a cysteine to serine mutation at position 33 which corresponds to position 3 in the pro-TGF- β 1 which according to Brunner *et al.* consists of residues 30-390, thus fulfills the limitation of a cysteine residue within the first ten amino acid residues of the pro-TGF β polypeptide. Thus the technical feature of the invention first claimed is not a special technical feature as required under PCT Rule 13.2." However, the Office fails to account for the third element of claim 1 in its analysis of the common special technical feature of the pending claims. All of the claims include this element, either expressly or via dependency (Applicants note that claims 20 and 22 are amended herein to clarify the scope of each claim and expressly recite this element).

When the technical features of claim 1 are considered collectively, it is apparent that the restriction requirement is improper. Neither EP0373994 nor Brunner *et al.* discloses an isolated polynucleotide encoding a mammalian pro-TGF β polypeptide, wherein the polynucleotide does not encode a cysteine residue within the first ten amino acid residues of the pro-TGF β polypeptide and also encodes a heterologous signal polypeptide that is in frame with the pro-

TGF β polynucleotide. Thus, the pending claims do meet the requirements of PCT Rules 13.1 and 13.2. Accordingly, the restriction requirement is improper and should be withdrawn.

If the Office somehow maintains the restriction requirement, then in the alternative, applicants request rejoinder of Group I and Group II (claims 1-16) in view of the common special technical feature among these claims (a polynucleotide encoding a mammalian pro-TGF β polypeptide, wherein the polynucleotide does not encode a cysteine residue within the first ten amino acid residues of the pro-TGF β polypeptide and also encodes a heterologous signal polypeptide that is in frame with the pro-TGF β polynucleotide).

Required election:

In response to the restriction requirement, Applicants elect the claims of Group II. Claims 14, 15 and 16 are encompassed by the elected Group. Applicants make this election with the understanding, as expressly stated by the Office and as required by MPEP 821.04(b), that any withdrawn claim directed to a process for making a peptide of Group II will be rejoined provided that the corresponding peptide of Group II is found to be allowable.

If in view of the reasoning provided herein, the Office rejoins the claims of Groups I and II, then applicant would elect the rejoined group consisting of claims 1-16. This election would also be made with the understanding that any withdrawn claim directed to a process for making a peptide will be rejoined provided that the corresponding peptide is found to be allowable.

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PATENT

Conclusion

This response addresses all of the requirements provided by the office action of August 11, 2011 and places the application in condition for examination on the merits. Should the examiner have any additional questions or issues to be considered, please contact the undersigned attorney at your earliest convenience.

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